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DESIGN, DEVELOPMENT AND EVALUATION OF ESSENTIAL OIL-BASED NASAL INHALER FOR SLEEP WELLNESS

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ABSTRACT

Sleep disorders have become a major health concern due to stress, anxiety, sedentary lifestyles, and prolonged screen exposure. Although conventional hypnotic drugs effectively manage insomnia, their long-term use is associated with adverse effects such as tolerance, dependence, cognitive impairment, and withdrawal symptoms. Consequently, there is growing interest in safer, natural alternatives. Aromatherapy, which uses volatile essential oils through inhalation, promotes relaxation and may improve sleep by stimulating the olfactory system and limbic region of the brain. This study aimed to formulate and evaluate a herbal nasal inhaler containing lavender (*Lavandula angustifolia*) and mace (*Myristica fragrans*) essential oils for relaxation and sleep wellness. Virgin coconut oil and olive oil were used as carrier oils to enhance stability and minimize the evaporation of volatile components. Two formulations with different essential oil ratios were prepared using the absorption impregnation technique by saturating sterile cotton wicks and assembling them into portable nasal inhalers. The formulations were evaluated for organoleptic properties, Thin Layer Chromatography (TLC), leakage resistance, aroma retention, and short-term stability. Both inhalers exhibited a pleasant floral-spicy aroma, clear appearance, and uniform wick saturation. TLC confirmed the presence of characteristic phytoconstituents, verifying the authenticity of the essential oils. The inhalers remained leak-proof under different storage conditions, retained their fragrance throughout the 30-day study, and showed no phase separation or changes in appearance or odour. Overall, the herbal nasal inhaler demonstrated satisfactory quality, stability, and packaging integrity, indicating its potential as a convenient, economical, and natural aromatherapy product for promoting relaxation and supporting healthy sleep.

KEYWORDS: Aromatherapy, Essential oils, Lavender oil, Mace oil, Nasal inhaler, Sleep wellness, Thin Layer Chromatography.

1. INTRODUCTION

Good sleep is important for maintaining physical and mental health. Today, many people suffer from poor sleep because of stress, busy lifestyles, excessive screen time, and irregular daily routines. Although medicines are available to treat insomnia, long-term use may cause side effects such as dependence, drowsiness, and reduced concentration. Therefore, there is increasing interest in natural and safer alternatives.

Aromatherapy is a natural method that uses essential oils to promote relaxation and improve sleep. When inhaled, the aroma reaches the olfactory system and stimulates the brain areas responsible for emotions and sleep. Lavender essential oil is well known for its calming and sleep-promoting effects, while mace essential oil possesses antioxidant, anxiolytic, and mild sedative properties. Combining these two essential oils may provide better relaxation and sleep support.

Nasal inhalers are small, portable, and easy-to-use devices that deliver essential oils directly to the nose, providing a quick aromatherapy effect. Carrier oils such as virgin coconut oil and olive oil help reduce evaporation and improve the stability of the formulation.

Therefore, the present study was undertaken to develop a herbal nasal inhaler containing lavender and mace essential oils. The prepared formulations were evaluated for their appearance, TLC profile, leakage resistance, aroma retention, and short-term stability to determine their suitability as a natural aromatherapy product for relaxation and sleep wellness.

2. MATERIALS AND METHODS

2.1 Materials

Lavender (*Lavandula angustifolia*) and mace (*Myristica fragrans*) essential oils were selected as the active ingredients due to their reported sedative, anxiolytic, and calming properties. **Virgin coconut oil** and **extra virgin olive oil** were used as carrier oils to improve absorption, reduce evaporation of volatile constituents, and provide sustained aroma release. Sterile absorbent cotton wicks and commercially available plastic nasal inhaler tubes served as the delivery system. Glass capillary tubes, calibrated micropipettes, sterile droppers, Petri dishes, glass rods, beakers, measuring cylinders, forceps, and other laboratory equipment available in the Department of Pharmaceutics, Vignan Pharmacy College (Autonomous), Vadlamudi, were used. All chemicals and reagents were of **analytical grade** and used without further purification.

2.2 Methods

2.2.1 Selection of Herbal Ingredients

The herbal ingredients were selected based on their reported pharmacological activities, safety, and suitability for inhalation aromatherapy. Lavender essential oil was chosen for its anxiolytic, sedative, and sleep-promoting effects, mainly attributed to linalool and linalyl acetate, which enhance GABA-mediated neurotransmission and promote relaxation. Mace (*Myristica fragrans*) essential oil contains bioactive compounds such as myristicin, elemicin, sabinene, α-pinene, and limonene, which exhibit antioxidant, neuroprotective, anxiolytic, and mild sedative properties. Virgin coconut oil and olive oil were used as carrier oils due to their oxidative stability, compatibility with essential oils, and ability to reduce volatilization, ensuring uniform absorption into the cotton wick and sustained aroma release during inhalation.

2.2.2 Formulation Design

Two formulations (F1 and F2) were designed by varying the proportions of lavender and mace essential oils while maintaining the same dosage form and delivery system. The objective of preparing multiple formulations was to optimize aroma intensity, fragrance persistence, physical stability, and overall user acceptability.

Lavender oil was incorporated as the primary calming component because of its pleasant floral aroma and documented sleep-promoting properties. Mace essential oil was included to provide complementary sedative and relaxing effects together with its warm spicy fragrance. The carrier oils were incorporated in suitable proportions to ensure adequate dilution of the essential oils, improve handling characteristics, reduce volatility, and facilitate uniform impregnation of the cotton wick.

The composition of the developed formulations is presented in Table 1.

Table 1: Composition of Essential Oil-Based Sleep Wellness Nasal Inhaler.

Ingredient	F1	F2
Lavender essential oil	5 drops	8 drops
Mace essential oil	10 drops	8 drops
Virgin coconut oil	5 drops	—
Olive oil	6 drops	4 drops
Sterile absorbent cotton wick	q.s.	q.s.
Plastic nasal inhaler tube	1	1

Figure 1: Impregnation of Cotton Wick with Essential Oil Blend.

2.2.3 Preparation of Essential Oil-Based Nasal Inhaler

The nasal inhalers were prepared by a simple absorption impregnation technique under hygienic laboratory conditions. Lavender and mace essential oils were accurately measured and mixed with predetermined quantities of virgin coconut oil and olive oil in an amber glass vial to obtain a homogeneous solution. A sterile absorbent cotton wick was gradually impregnated with the prepared blend and allowed to stand for 2–3 minutes for uniform absorption. The saturated wick was then inserted into a sterile plastic nasal inhaler using sterilized forceps, and the inhaler was tightly sealed to minimize evaporation of volatile constituents during storage. Each formulation was designated as either F1 or F2 and labelled for easy identification. The formulations were stored in tightly sealed containers at room temperature (25 ± 2°C) and kept protected from sunlight, excess heat, and moisture until they were evaluated for their physicochemical.

Figure 2: Prepared Herbal Essential Oil-Based Nasal Inhaler Formulations (F1 and F2).

2.3 Evaluation of the Formulated Nasal Inhaler

To evaluate their overall quality and performance, the prepared formulations were examined for physicochemical properties, packaging integrity, aroma retention, chromatographic profile, and stability during storage. Their suitability as herbal aromatherapy nasal inhalers was then assessed.

2.3.1 Organoleptic Evaluation

Organoleptic evaluation was performed immediately after formulation to assess the physical and sensory characteristics of the nasal inhalers. The formulations were examined for colour, clarity, appearance, and uniform wick saturation under normal daylight. Aroma was evaluated by three healthy volunteers with normal olfactory function by inhaling from a distance of 2–3 cm for 3 seconds. Fragrance was assessed for pleasantness, intensity, freshness, and overall acceptability, and the observations were recorded for comparison between formulations.

2.3.2 Thin Layer Chromatography (TLC)

Thin-layer chromatography (TLC) was performed to confirm the identity of the essential oils and detect their characteristic phytoconstituents. Precoated silica gel 60 F_{254} aluminium plates were used as the stationary phase, while hexane:ethyl acetate (8:2, v/v) served as the mobile phase. Approximately 5 µL of each essential oil was applied onto the plate using glass capillary tubes. The TLC chamber was pre-saturated with the mobile phase for 20 minutes, and chromatographic development was carried out until the solvent front migrated about 8 cm. The developed plate was air-dried, sprayed with vanillin–sulphuric acid reagent, and heated at 105°C for 5 minutes. The separated spots were observed under visible light, and their colour, number, migration distance, and Rf values were recorded for identification and quality assessment. The retention factor (Rf) values were calculated using the equation:

$$Rf = \frac{\text{Distance travelled by the compound}}{\text{Distance travelled by the solvent front}}$$

The observed chromatographic pattern and Rf values were compared with reported literature to confirm the identity, purity, and quality of the selected essential oils.

2.3.3 Leakage Test

The leakage test was carried out to evaluate the integrity of the nasal inhaler container and the effectiveness of its

sealing system in preventing the loss of volatile essential oils. The prepared inhalers were tightly capped and stored at 25 ± 2°C in upright, horizontal, and inverted positions for 24 hours to simulate handling and storage conditions. After the test period, each inhaler was visually inspected for leakage around the cap, body, and base. The external surface was wiped with filter paper to detect any oily residues, and the wick compartment was examined for seepage. The inhalers were considered satisfactory if no visible leakage, oily stains, or external wetting was observed, indicating effective sealing and compatibility of the formulation with the packaging material.

2.3.4 Aroma Retention Study

The formulated nasal inhalers were evaluated for aroma retention to assess the stability of the essential oil fragrance during storage. Inhalers were stored in airtight containers at 25 ± 2°C, protected from light, heat, and moisture. Aroma was assessed on Day 0, 15, and 30 by five healthy volunteers (22–35 years) with normal olfactory function. Each volunteer inhaled the formulation from 2–3 cm for 3 seconds, with a 1-minute interval between samples to avoid olfactory fatigue. Aroma intensity, pleasantness, freshness, and overall acceptability were recorded. The formulation was considered satisfactory if the characteristic floral-spicy aroma remained perceptible without the development of off-odours throughout the storage period.

2.3.5 Stability Study

The physical stability of the herbal nasal inhalers was evaluated by storing the formulations in airtight containers at 25 ± 2°C for 30 days, protected from light, heat, and moisture. Samples were assessed on Day 0, 15, and 30 for colour, appearance, odour, cotton wick condition, leakage, and fragrance retention. The inhalers were visually examined for discoloration, phase separation, or other signs of instability, while the cotton wick and inhaler container were inspected for uniform saturation, drying, deformation, cracking, or leakage to ensure formulation stability during storage. The fragrance was also assessed during each observation period to determine whether prolonged storage resulted in any appreciable reduction in aroma intensity. The formulation was considered physically stable when no significant changes in appearance, odour, wick condition, or packaging integrity were observed throughout the storage period.

2.3.6 Statistical Analysis

All applicable experiments were conducted in triplicate to ensure the reliability and reproducibility of the results. The experimental findings were expressed as mean ± standard deviation (Mean ± SD), and descriptive statistical analysis was carried out using Microsoft Excel (Microsoft Corporation, USA). The collected data were summarized in the form of tables to facilitate comparison between the developed formulations.

3. RESULTS

3.1 Organoleptic Evaluation

The prepared herbal sleep wellness nasal inhalers were successfully formulated using the absorption impregnation technique. Both formulations (F1 and F2) exhibited satisfactory organoleptic characteristics with a clear appearance and pale yellow colour. The cotton wicks were uniformly impregnated with the essential oil blend without any dry patches or uneven distribution. The inhalers produced a pleasant floral-spicy aroma that was considered acceptable by all evaluators. Immediately after preparation, the formulations were free from visible particulate matter, discoloration, and phase separation, demonstrating the successful and uniform incorporation of the essential oils into the carrier system.

Table 2: Organoleptic Evaluation of the Formulated Nasal Inhalers.

Parameter	Observation
Colour	Pale yellow
Appearance	Clear
Odour	Pleasant floral-spicy aroma
Cotton wick	Uniformly saturated

The results indicated that the selected carrier oils provided a homogeneous formulation with good aesthetic appearance and acceptable fragrance characteristics.

3.2 Thin Layer Chromatography (TLC)

Thin Layer Chromatography (TLC) was carried out to verify the presence of characteristic phytoconstituents in lavender and mace essential oils. After derivatization with vanillin–sulphuric acid reagent followed by heating, distinct chromatographic spots were obtained. Lavender essential oil showed two prominent spots with Rf values of 0.46 and 0.71, while mace essential oil exhibited two characteristic spots with Rf values of 0.39 and 0.67. The obtained TLC profiles indicated effective separation of volatile components and confirmed characteristic chromatographic profiles of both essential oils.

Table 3: Thin Layer Chromatographic Profile of Essential Oils.

Sample	Observation	Rf Value
Lavender essential oil	Purple-blue spot	0.46
Lavender essential oil	Light violet spot	0.71
Mace essential oil	Brownish-purple spot	0.39
Mace essential oil	Dark violet spot	0.67

The chromatographic profiles obtained for both essential oils were distinct and reproducible, indicating good quality and suitability of the selected herbal ingredients for formulation development.

3.3 Leakage Test

The leakage study demonstrated that both formulations remained intact during storage under upright, horizontal, and inverted conditions. No leakage of the essential oil blend was observed around the cap, body, or wick compartment of the inhaler tubes. The filter paper test also showed the absence of oil stains, confirming satisfactory sealing efficiency of the packaging system.

Table 4: Leakage Test.

Parameter	Observation
Leakage	Not observed
Seal integrity	Satisfactory

These findings indicate that the inhaler container effectively retained the volatile formulation during storage and handling.

3.4 Aroma Retention Study

The formulated inhalers retained their characteristic floral-spicy aroma throughout the study period. Aroma intensity remained excellent during the initial evaluation and after 15 days of storage. A slight reduction in fragrance intensity was observed after 30 days; however, the aroma remained pleasant and readily perceptible. No development of unpleasant odour was detected during storage.

Table 5: Aroma Retention Study.

Storage period	Observation
Initial	Excellent
15 Days	Excellent
30 Days	Good

The results demonstrated satisfactory fragrance retention, indicating that the carrier oils and airtight inhaler container effectively minimized the evaporation of volatile constituents.

3.5 Stability Study

The physical stability of the developed herbal sleep wellness nasal inhalers was evaluated over a period of 30 days under ambient storage conditions (25 ± 2°C). Both formulations (F1 and F2) retained their physical stability throughout the study period without any visible signs of deterioration. Their colour, appearance, and odour remained unchanged during storage. The cotton wick also remained uniformly saturated, with no evidence of drying, shrinkage, or discoloration, demonstrating effective retention of the essential oil blend. Furthermore, no phase separation or leakage of the formulation was detected, demonstrating good compatibility between the formulation and the packaging system. Although a slight reduction in fragrance intensity was observed after 30 days, the characteristic floral-spicy aroma remained pleasant and readily perceptible. These observations indicate that the developed formulations remained physically stable under the prescribed storage conditions for the duration of the study.

Table 6: Stability Evaluation of the Formulated Herbal Sleep Wellness Nasal Inhalers.

Parameter	Initial	15 Days	30 Days
Colour	Pale yellow	No change	No change
Appearance	Clear	No change	No change
Odour	Pleasant floral-spicy aroma	No significant change	Slight reduction in intensity; pleasant aroma retained
Cotton wick condition	Uniformly saturated	Uniformly saturated	Uniformly saturated; no drying or discoloration
Leakage	Absent	Absent	Absent
Phase separation	Absent	Absent	Absent

The formulations remained physically stable throughout the 30-day storage period, exhibiting no significant changes in colour, appearance, packaging integrity, or wick condition. The slight decrease in aroma intensity observed after prolonged storage is expected due to the gradual volatilization of essential oil constituents and did not adversely affect the overall quality or acceptability of the nasal inhalers.

4. DISCUSSION

The present study successfully developed and evaluated an essential oil-based nasal inhaler for promoting relaxation and sleep wellness through aromatherapy. Lavender (*Lavandula angustifolia*) and mace (*Myristica fragrans*) essential oils were selected due to their reported anxiolytic, sedative, antioxidant, and neuroprotective properties. Lavender exerts its calming effects mainly through linalool and linalyl acetate, while mace contains bioactive constituents such as myristicin, elemicin, sabinene, and α-pinene, which contribute to relaxation and sleep enhancement.

Both formulations exhibited acceptable organoleptic characteristics, including a clear appearance, uniform wick saturation, and a pleasant floral-spicy aroma, indicating good compatibility between the essential oils and carrier oils. Virgin coconut oil and olive oil aided in uniform blending and reduced rapid evaporation of volatile constituents.

TLC analysis confirmed the presence of characteristic phytoconstituents with consistent chromatographic

profiles, supporting the authenticity and quality of the essential oils. The leakage test showed no oil leakage in upright, horizontal, or inverted positions, demonstrating effective packaging integrity.

The aroma retention study indicated that the characteristic fragrance remained perceptible throughout the 30-day storage period, with only a slight reduction in intensity due to the natural volatilization of essential oils. Carrier oils likely contributed to improved aroma persistence. Stability studies further confirmed that the formulations maintained their appearance, odour, wick condition, and packaging integrity without leakage or phase separation during storage.

Overall, the developed nasal inhaler demonstrated satisfactory physicochemical properties, stability, and packaging performance, indicating its potential as a convenient, portable, and natural aromatherapy product for relaxation and sleep wellness. Further clinical studies are required to establish its therapeutic efficacy in individuals with sleep disturbances.

5. CONCLUSION

This study successfully formulated and evaluated a herbal nasal inhaler containing lavender and mace essential oils, highlighting its potential as a natural aromatherapy-based approach for promoting sleep wellness. The formulated inhalers exhibited satisfactory organoleptic characteristics, confirmed phytochemical authenticity by Thin Layer Chromatography, demonstrated effective leakage resistance, retained their characteristic aroma during storage, and remained physically stable under ambient conditions for 30 days. The combination of lavender and mace essential oils, together with coconut oil and olive oil as carrier oils, resulted in a stable and user-friendly inhalation system capable of delivering pleasant aromatic vapours. The developed formulation represents a promising natural aromatherapy product that may contribute to relaxation and improved sleep quality. Further pharmacological and clinical evaluation is required to confirm the therapeutic efficacy, long-term stability, safety, and patient acceptability of the formulation before it can be considered for commercial application.

6. Future Scope

Future studies should characterize the essential oil constituents using **GC–MS** to establish their chemical profile. Randomized clinical trials in individuals with sleep disturbances should be conducted to evaluate efficacy using standardized tools such as the **Pittsburgh Sleep Quality Index (PSQI)**. Accelerated and long-term stability studies as per **ICH guidelines** are recommended to determine shelf life. Further research may also focus on optimizing essential oil concentrations, exploring additional synergistic botanicals, developing biodegradable inhaler devices, and commercializing standardized herbal aromatherapy inhalers.

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Conflict of Interest

The authors confirm that there are no conflicts of interest associated with the publication of this research work.

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Authors' Contributions

All authors contributed significantly to the conception and design of the study, formulation development, experimental work, data collection, data interpretation, manuscript preparation, critical revision of the article, and approval of the final version for publication. All authors agree to be accountable for all aspects of the work.

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